JUL - 5 2000

K001110

510(k) SUMMARY

The Summary of Safety and Effectiveness on the Crystal-EEG® Model 15 reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Robert N. Schmidt, President Cleveland Medical Devices 11000 Cedar Avenue Cleveland, Ohio 44106
Telephone	216/791-6720
Facsimile	216/791-6744
Date	April 5, 2000
Name	Crystal-EEG® Model 15
Classification	Electroencephalograph, 21 CFR 882.1400
Predicate:	Crystal – EEG Model 10, 510(k) K970672
Description	The Crystal-EEG® Model 15 wireless system allows extended EEG monitoring without having the subject tethered with wires. The device consists of a Transmitter, a Receiver Assembly (the receiver, receiver cable, and power supply), accessories (Electrode cable, mounting band, electrolyte gel, screwdriver, batteries, and signal generator Test Pack), and a PC Operator Interface Software program. The Transmitter (Patient Unit) collects signals from electrodes attached to the patient performs analog-to-digital conversion, encoding, formatting, and transmitting of all signals. The signals are communicated using a 902-928 MHz radio transmitter. Over one hundred transmitters can be used in the same area without interference with one another. The Receiver Assembly receives the transmitted data packet, performs error detection / correction, then sends the data through a Receiver cable to the PC Operator interface in ASCII format where the collected data can be displayed or stored. The Crystal-EEG® Model 15 Capture program consists of several software components which allow the user to acquire, store, view, and export EEG data as acquired by the Crystal-EEG® Model 15 Transmitter. The software provides a simple graphical interface for setting up and controlling data acquisition. Crystal-EEG® is a registered trademark of Cleveland Medical Devices Inc. Cleveland, Ohio
Intended Use	The Crystal-EEG® Model 15 is a mobile, intermediate range, wireless EEG system intended to be used for measuring and transmitting electroencephalogram (EEG) signals.

510(k) SUMMARY, continue

The Summary of Safety and Effectiveness on the Crystal-EEG® Model 15 reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Contraindications	Below:

Frequency of Transmitter **Rated Maximum Output Power of Transmitter watts**	**150 kHz to 80 MHz** **Separation Distance metres**	**150 kHz to 800 MHz** **Separation Distance metres**	**800 MHz to 1.04 GHz** **Separation Distance metres**
0.01	0.4	12	23
0.1	1.1	37	74
1	3.5	117	233
10	11.1	369	738
100	35	1167	2333
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Technological Characteristics	The device subjected to the following voluntary standards to ensure the efficacy and safety of the device for its intended use. • FCC Part 15.109, Class B digital device; • FCC Part 15.249, Intentional radiator, FCC ID# N9Y0007; • IEC 60601-1-2 Medical Electrical Equipment, Part 1 General requirements for safety. The device was tested to and results are provided for the following tests: • EN 61000-4-2: 1995 Electrostatic discharge immunity test; • EN 61000-4-3: 1995 Radiated, radio-frequency, electromagnetic field immunity test; • EN 61000-4-4: 1995 Electrical fast transient / burst immunity tests; • EN 61000-4-6: 1996 Immunity to conducted disturbances, Induced by radio-frequency fields; • EN-55011 Electromagnetic Emissions; and • IEC 601-2-26 only to the requirements of environmental conditions in regards to ambient temperature range (10° to 50° C) and Humidity (25% to 95%, without condensation).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2000

Mr. Robert N. Schmidt
President
Cleveland Medical Devices, Inc.
11000 Cedar Avenue
Cleveland, Ohio 44106

Re: K001110
Trade Name: Crystal-EEG® Model 15
Regulatory Class: II
Product Code: GWQ
Dated: April 5, 2000
Received: April 6, 2000

Dear Mr. Schmidt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lachman

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001110

Device Name: Crystal-EEG® Model 15

Indications For Use:

The Crystal-EEG® Model 15 is a mobile, intermediate range, wireless EEG system intended to be used for measuring and transmitting electroencephalogram (EEG) signals.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K001110

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)